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| APPLICATION NO.                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/583,439                         | 06/16/2006  | Silvo Zupancic       | 4061-33PUS          | 6654             |
| 27799                              | 7590        | 08/21/2007           | EXAMINER            |                  |
| COHEN, PONTANI, LIEBERMAN & PAVANE |             |                      | BARTS, SAMUEL A     |                  |
| 551 FIFTH AVENUE                   |             |                      | ART UNIT            | PAPER NUMBER     |
| SUITE 1210                         |             |                      |                     | 1621             |
| NEW YORK, NY 10176                 |             |                      |                     |                  |
|                                    |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                    |             |                      | 08/21/2007          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 10/583,439      | ZUPANCIC, SILVO |
|                              | Examiner        | Art Unit        |
|                              | Samuel A. Barts | 1621            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dolitzky (WO 02/45658 and US 6,924,393).

The instant claims are directed to a process for preparing venlafaxine that comprises the conversion of a venlafaxine precursor in the presence of a salt of formic acid wherein the molar ratio of the salt of formic acid to the venlafaxine precursor is 0.3-10 to 1.

The prior art of Dolitzky discloses a process for preparing venlafaxine which comprises the conversion of a venlafaxine precursor in the presence of a salt of formic acid wherein the molar ratio of the salt of formic acid does not fall within the claimed range. See example 2 on page 7.

Thus the instant claims differ from the prior art by using different mole ratios of reactants. This difference is not sufficient to render the claims patentable because varying the mole ratio of reactants is a standard practice to an ordinary artisan in the field of organic synthetic chemistry. Normally, change in temperature, concentration, or both, is not patentable modification; however, such changes may impart patentability to process if ranges claimed produce new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving

such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if modification was within capabilities of one skilled in art; more particularly, where general conditions of claim are disclosed in prior art, it is not inventive to discover optimum or workable ranges by routine experimentation

Thus, it would have been obvious to one having ordinary skill in the art at the time that applicant's invention was made to have varied the mole ratio of formic acid in the invention of Dolitzky with a reasonable expectation of making venlafaxine. One skilled in the art would have motivated to make such a change in order to optimize the process. Furthermore, it has been held that: "*Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality.*" In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A. Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel A Barts/  
Primary Examiner  
Art Unit 1621

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